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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
STRZELECKA, TERESA E	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 09/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/613,076	NI ET AL.	
	Examiner	Art Unit	
	Teresa E. Strzelecka	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-24 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I Groups 1-34, claims 1-10, 14, 15 and 21, all in part, drawn to an isolated nucleic acid comprising a polynucleotide having a sequence at least 95% identical to a sequence selected from the group consisting of:

(a) a polynucleotide fragment of SEQ ID NO:X or a polynucleotide fragment of the cDNA sequence contained in ATCC Deposit NO:Z, which is hybridizable to SEQ ID NO:X;

(b) a polynucleotide encoding a polypeptide fragment of SEQ ID NO:Y or a polypeptide fragment encoded by the cDNA sequence contained in cDNA ATCC Deposit NO:Z, which is hybridizable to SEQ ID NO:X;

(c) a polynucleotide encoding a polypeptide domain of SEQ ID NO: Y or a polypeptide domain encoded by the cDNA sequence contained in cDNA ATCC Deposit NO:Z, which is hybridizable to SEQ ID NO:X;

(d) a polynucleotide encoding a polypeptide epitope of SEQ ID NO:Y or a polypeptide epitope encoded by the cDNA sequence contained in cDNA ATCC Deposit NO:Z, which is hybridizable to SEQ ID NO:X;

(e) a polynucleotide encoding a polypeptide of SEQ ID NO:Y or the cDNA sequence contained in cDNA ATCC Deposit NO:Z, which is hybridizable to SEQ I.D NO:X, having biological activity;

(f) a polynucleotide which is a variant of SEQ ID NO:X;

(g) a polynucleotide which is an allelic variant of SEQ ID NO:X;

(h) a polynucleotide which encodes a species homologue of the SEQ ID NO:Y;

(i) a polynucleotide capable of hybridizing under stringent conditions to any one of the polynucleotides specified in (a)-(h), wherein said polynucleotide does not hybridize under stringent conditions to a nucleic acid molecule having a nucleotide sequence of only A residues or of only T residues, classified, for example, in class 536, subclass 23.1.

If Group 1 is elected, this correlates to Gene No 1, cDNA ATCC Deposit 203364, wherein X is 11 and Y is 45.

If Group 2 is elected, this correlates to Gene No 2, cDNA ATCC Deposit 203364, wherein X is 12 and Y is 46.

II. Groups 35-68, claim(s) 11, 12 and 16, all in part, each group directed to polypeptide comprising an amino acid sequence at least 90% identical to a sequence selected from the group consisting of:

(a) a polypeptide fragment of SEQ ID NO:Y or the encoded sequence included in ATCC Deposit NO:Z;

(b) a polypeptide fragment of SEQ ID NO:Y or the encoded sequence included in ATCC Deposit NO:Z, having biological activity;

(c) a polypeptide domain of SEQ ID NO:Y or the encoded sequence included in ATCC Deposit NO:Z;

(d) a polypeptide epitope of SEQ ID NO:Y or the encoded sequence included in ATCC Deposit NO:Z;

(e) a secreted form of SEQ ID NO: Y or the encoded sequence included in ATCC Deposit NO:Z;

(f) a full length protein of SEQ ID NO:Y or the encoded sequence included in ATCC Deposit NO:Z;

(g) a variant of SEQ ID NO:Y;

(h) an allelic variant of SEQ ID NO:Y; or

(i) a species homologue of the SEQ ID NO:Y, classified, for example, in class 530, subclass 300, for example.

If Group 35 is elected, this correlates to Gene No 1, cDNA ATCC Deposit 203364 of Table 1, wherein X is 11 and Y is 45.

If Group 36 is elected, this correlates to Gene No 2, cDNA ATCC Deposit 203364, wherein X is 12 and Y is 46.

III. Groups 69-102, claim 13, in part, drawn to an isolated antibody which binds to a protein with SEQ ID NO Y, classified, for example, in class 530, subclass 387.1.

If Group 69 is elected, this correlates to Gene no 1, cDNA ATCC Deposit 203364, wherein X is 11 and Y is 45.

If Group 70 is elected, this correlates to Gene No 2, cDNA ATCC Deposit 203364, wherein X is 12 and Y is 46.

IV. Groups 103-136, claim 24, in part, drawn to a method for preventing, treating or ameliorating an undefined medical condition by administering a polynucleotide of SEQ ID NO X, classified, for example, in class 514, subclass 2.

If Group 103 is elected, this correlates to Gene no 1, cDNA ATCC Deposit 203364, wherein X is 11 and Y is 45.

If Group 104 is elected, this correlates to Gene No 2, cDNA ATCC Deposit 203364, wherein X is 12 and Y is 46.

V. Groups 137-170, claim 17, in part, drawn to a method for preventing, treating or ameliorating an undefined medical condition by administering a polypeptidetide of SEQ ID NO Y, classified, for example, in class 514, subclass 2, for example.

If Group 137 is elected, this correlates to Gene no 1, cDNA ATCC Deposit 203364, wherein X is 11 and Y is 45.

If Group 138 is elected, this correlates to Gene No 2, cDNA ATCC Deposit 203364, wherein X is 12 and Y is 46.

VI. Groups 171-204, claim 18, in part, drawn to a method of diagnosis of an undefined pathological condition by determining the presence or absence of a mutation in a polynucleotide of SEQ ID NO X, classified, for example, in class 435, subclass 6.

If Group 171 is elected, this correlates to Gene no 1, cDNA ATCC Deposit 203364, wherein X is 11 and Y is 45.

If Group 172 is elected, this correlates to Gene No 2, cDNA ATCC Deposit 203364, wherein X is 12 and Y is 46.

VII. Groups 205-238, claim 19, in part, drawn to a method of diagnosis of an undefined pathological condition by determining the presence or amount of expression of a polypeptide of SEQ ID NO Y, classified, for example, in class 435, subclass 7.1.

If Group 205 is elected, this correlates to Gene no 1, cDNA ATCC Deposit 203364, wherein X is 11 and Y is 45.

If Group 206 is elected, this correlates to Gene No 2, cDNA ATCC Deposit 203364, wherein X is 12 and Y is 46.

VIII. Groups 239-272, claim 20, in part, drawn to a method of identifying a binding partner to a polypeptide defined by SEQ ID NO Y, classified, for example, in class 436, subclass 501.

If Group 239 is elected, this correlates to Gene no 1, cDNA ATCC Deposit 203364, wherein X is 11 and Y is 45.

If Group 240 is elected, this correlates to Gene No 2, cDNA ATCC Deposit 203364, wherein X is 12 and Y is 46.

IX. Groups 273-306, claim 22, in part, drawn to a method of identifying an activity in a biological assay by identification of the protein in the supernatant wherein the cell expresses a polypeptide encoded by SEQ ID NO X, classified, for example, in class 436, subclass 86.

If Group 273 is elected, this correlates to Gene no 1, cDNA ATCC Deposit 203364, wherein X is 11 and Y is 45.

If Group 274 is elected, this correlates to Gene No 2, cDNA ATCC Deposit 203364, wherein X is 12 and Y is 46.

X. Groups 307-340, claim 23, in part, drawn to a binding partner to a polypeptide defined by SEQ ID NO Y, classified, for example, in class 436, subclass 501.

If Group 307 is elected, this correlates to Gene no 1, cDNA ATCC Deposit 203364, wherein X is 11 and Y is 45.

If Group 308 is elected, this correlates to Gene No 2, cDNA ATCC Deposit 203364, wherein X is 12 and Y is 46.

The inventions are distinct, each from the other because of the following reasons:

1. Inventions (1-34) and (35-68) are separate and distinct because the inventions are directed to different chemical types regarding the critical limitations therein. For Groups (1-34), the critical feature is a polynucleotide whereas for Groups (35-68) the critical feature is a polypeptide. It is acknowledged that various processing steps may cause a polypeptide of Groups (35-68) to be directed as to its synthesis by a polynucleotide of Groups (1-34), however, the completely separate chemical types of the inventions of Groups (1-34) and (35-68) supports the undue search burden if both were examined together. Additionally, polypeptides have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if examiner together, as compared to being searched separately. Also, it is pointed out that processing that may connect two groups does not prevent them from being viewed as distinct, because enough processing can result in producing any composition from any other composition if the processing is not so limited to additions, subtractions, enzyme actions, etc. The search burden in terms of searching for both polypeptides and polynucleotides with disclosed sequences would be serious, since the searches for polypeptide sequences and polynucleotide sequences are not coextensive.

2. Inventions (1-34) and (69-102 and 307-340) are separate and distinct, as the claims of Groups (1-34) are drawn to polynucleotides, while the claims of Groups (69-102) are drawn to an antibody, and claims of Groups (307-340) are drawn to a binding partner of a polypeptide. These are differing biochemical entities having differing biochemical properties, structures and effects. Inventions (69-102) and (307-340) would require searching in areas unrelated to polynucleotides, and as such, would require an undue burden on the examiner if not restricted. First, antibodies and polynucleotides are different biochemical entities, the structures of which

are composed of amino acids and nucleotides, respectively. Their functions are entirely different. Therefore, search for a polynucleotide would not be coextensive with a search for an antibody, presenting a considerable search burden. Further, since the binding partner of a polypeptide can be a protein or a small molecule, searching for polynucleotides or antibodies would not be coextensive with searching for small molecules which might bind to a protein or searching for other proteins which bind to it, again causing a considerable search burden.

3. Inventions (1-34) and (137-170, 205-238 and 239-272) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the polynucleotides of Groups (1-34) are not required for the methods of Groups (137-170, 205-238 and 239-272).

4. Inventions (1-34) and (103-136, 171-204 and 273-306) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of Groups (1-34) could be used for an entirely different purpose such as in making the polypeptides of Groups (35-68), rather than in the methods of Groups (103-136, 171-204 and 273-306).

The inventions of Groups (1-34) and (103-136, 171-204 and 273-306) have separate status in the art as shown by their different classification. Searching the inventions of Groups (1-34) and (103-136, 171-204 and 273-306) together would impose a serious search burden. The

search for Groups 103-136, for example, would require a text search for a method of preventing, treating or ameliorating any medical condition potentially related to polynucleotides of Groups 1-34, search for Groups 171-204 would require a sequence and text search for all possible mutations in the polynucleotides of Groups 1-34, which are not claimed in Groups 1-34, and search for methods of Groups 273-306 would require searching for all possible biological activities related to the expression of polynucleotides from Groups 1-34, which are not related to the physical structure of polynucleotides themselves, imposing a serious search burden on the examiner.

5. Inventions (35-68) and (69-102) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are polypeptides and antibodies specific for the polypeptides, which are structurally and functionally distinct molecules. The polypeptides of Groups 35-68 contain potentially hundreds of regions to which an antibody may bind, while the antibodies of Groups 69-102 are defined in terms of their binding specificities to small regions of the polypeptides. Searching the polypeptides and antibodies would impose a serious search burden. The inventions have separate status in the art as shown by their different classification. A polypeptide and an antibody, which binds to it, require different searches. A sequence search for a polypeptide would not identify an antibody, which binds to it, and the search for an antibody may not uncover the polypeptide to which it binds, since antibodies for some polypeptides may be known without the polypeptides being known.

6. Inventions (35-68) and (137-170, 205-238 and 239-272) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Groups (35-68) could be used for an entirely different purpose such as production of antibodies of Groups (69-102), rather than in the method of Groups (137-170, 205-238 and 239-272). Searching Groups (35-68) with Groups 205-238, for example, would impose serious search burden. Search for Groups (205-238) would require search for all possible pathological conditions which might be related to polypeptides of Groups (35-68) and the relationship of all possible polypeptide fragments to the relationship with pathological conditions, all of which is unrelated to searches for sequences of Groups (35-68). Similarly, search for Groups (137-170), for example, would require a text search for a method of preventing, treating or ameliorating any medical condition potentially related to polypeptides of Groups (35-68), imposing serious search burden.

7. Inventions (35-68) and (307-340) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are a polypeptide and a polypeptide binding partner, and these are two different entities with different functions and different modes of operation. Therefore, search for polypeptides of Groups (35-68) would not be coextensive with a search for any molecule from Groups (307-340), and such molecules include other proteins, nucleic acids,

aptamers, small molecules, etc., imposing a serious search burden on the examiner. Conversely, search for a polypeptide with a given amino acid sequence would not lead to finding any ligands for that polypeptide.

8. Inventions (35-68) and (103-136, 171-204 and 273-306) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the polypeptides of Groups (35-68) are not required for the methods of Groups (103-136, 171-204 and 273-306).

9. Inventions (69-102) and (103-136 and 137-170) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the antibodies of Groups (69-102) are not required for the methods of Groups (103-136 and 137-170).

10. Inventions (103-136, 171-204, 205-238, 239-272, 273-306 and 137-170) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to methods which have different method steps, starting materials and goals. The methods of preventing, treating, or ameliorating a medical condition using a polynucleotide (Groups 103-136), methods of diagnosing a pathological condition using a polynucleotide

(Groups 171-204), methods of diagnosing a pathological condition using a polypeptide (Groups 205-238), methods of identifying a binding partner of a polypeptide (Groups 239-272), methods of identifying an activity in a biological assay (Groups 273-306) and methods of preventing, treating, or ameliorating a medical condition using a polypeptide (Groups 137-170). are all unrelated as they comprise distinct steps, and utilize different products, thus having different modes of operation. The methodology and materials used are different for each method. For example, diagnosis using polynucleotides involves either hybridization or amplification with nucleic acids primers or probes, diagnosis using expression of a polypeptide may be achieved using antibodies, and treatment of a disease using polynucleotides involves using vector vaccines, therefore the methods are divergent in materials and steps.

11. Inventions (307-340) and (103-136, 273-306, 137-170) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the binding partners of a polypeptide of Groups (307-340) are not required for the methods of Groups (103-136, 273-306, 137-170).

12. Inventions (307-340) and (239-272) are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the binding partner to a polypeptide can be identified by an entirely different

process, such as a computational modeling of the peptide-binding partner interaction, rather than by the methods of Groups (239-272).

13. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

14. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

15. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.45(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.45(b) and by the fee required under 37 CFR 1.17(i).

17. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E. Strzelecka whose telephone number is (571) 272-0789. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TERESA STRZELECKA
PATENT EXAMINER
Teresa Strzelecka

September 17, 2005